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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/302,896	04/30/1999	MICHAEL B. CHANCELLOR	2710-4007-US	7603

28089 7590 06/07/2004

WILMER CUTLER PICKERING HALE AND DORR LLP
300 PARK AVENUE
NEW YORK, NY 10022

EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.		Applicant(s)	
	09/302,896		CHANCELLOR ET AL.	
	Examiner		Art Unit	
	Sumesh Kaushal Ph.D.		1636	

All participants (applicant, applicant's representative, PTO personnel):

(1) Ex. Sumesh Kaushal.

(3) Leslie A. Serunian.

(2) PEx. Jeffrey Fredman.

(4) Magdalena Cilella.

Date of Interview: 02 June 2004.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: See all attachments +

Claim(s) discussed: Newly proposed claims 260-273.

Identification of prior art discussed: none

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

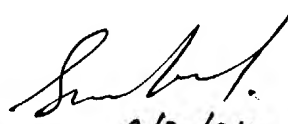
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

* Newly Proposed claims 260-273 were disagreed, the applicant is considering broadening the scope of claims that would put these claims in a condition of an allowance.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


6/2/04
Examiner's signature, if required

PTOL-413A (08-03)
Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 09/302,896 First Named Applicant: Michael B. CHANCELLOR
Examiner: Sumesh Kaushal, Ph.D. Art Unit: 1636 Status of Application: Pending

Tentative Participants:

(1) Leslie A. Serunian (2) Magdalena Cilella
(3) Examiner Kaushal (4) Examiner Fredman (SPE)

Proposed Date of Interview: June 2, 2004 Proposed Time: 2 PM (AM/PM)

Type of Interview Requested:

(1) ☐ Telephonic (2) ☒ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☐ YES ☒ NO

If yes, provide brief description: _____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>Section 112 Rej's</u>	<u>196-259 and</u>				
	<u>Newly proposed claims 260-273</u>				
(2) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Continuation Sheet Attached

Brief Description of Arguments to be Presented:

Please see attached set of proposed claims (3 pages) for discussion.

An interview was conducted on the above-identified application on _____.

NOTE:

This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Leslie A. Serunian
(Applicant/Applicant's Representative Signature)
Leslie A. Serunian, Reg. No. 35,353

(Examiner/SPE Signature)

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

+ Attachment Interview Summary

PROPOSED CLAIMS FOR EXAMINER INTERVIEW ON JUNE 2, 2004

PATENT
Docket No.: PIT-010
(Formerly 2710-4007US1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Michael B. CHANCELLOR et al.
Serial No. : 09/302,896 Art Unit: 1636
Filed : April 30, 1999 Examiner: Sumesh Kaushal, Ph.D.
For : **Muscle-Derived Cells (MDCs) for Treating Muscle- or Bone-Related Injury or Dysfunction (As Amended)**

IN THE CLAIMS:

Complete Listing and Status of the Claims

1.-259. Canceled

260. (New) A method of repairing urethra muscle tissue injury, damage, or dysfunction for ameliorating stress urinary incontinence, comprising:

introducing an enriched population of autologous skeletal muscle-derived myoblasts into a site of injured, damaged, or dysfunctional urethra muscle tissue of a recipient in need thereof, in an amount effective to repair the injured, damaged, or dysfunctional urethra muscle tissue to ameliorate stress urinary incontinence.

261. (New) The method according to claim 260, wherein the skeletal muscle-derived myoblasts are histocompatibly-matched with the recipient in need of treatment.

262. (New) The method according to claim 260, wherein the skeletal muscle-derived myoblasts are introduced in a composition comprising a physiologically acceptable medium.

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Express Mail Label No.: EV xxxxxxxx US

+ Attached to - Interview Summary

Applicants: Michael B. Chancellor et al.
U.S. Serial No.: 09/302,896
Filing Date: April 30, 1999

Docket No.: PIT-010
(Formerly: 2710-4007US1)

+ Attached to Interview Summary

263. (New) The method according to claim 260, wherein the skeletal muscle-derived myoblasts are introduced in an amount of about 10^5 to 10^6 cells per cm^3 of tissue to be treated in a physiologically acceptable medium.

264. (New) The method according to claim 260, wherein a cloned population of the skeletal muscle-derived myoblasts is introduced into the recipient.

265. (New) The method according to claim 260, wherein the skeletal muscle-derived myoblasts are subjected to a cytokine or growth factor selected from the group consisting of basic fibroblast growth factor (b-FGF), insulin-like growth factor (IGF), and nerve growth factor (NGF) prior to introducing the skeletal muscle-derived myoblasts into the recipient.

266. (New) The method according to claim 260, further comprising isolating the skeletal muscle-derived myoblasts according to a culture method comprising:

- (i) plating a suspension of skeletal muscle cells in a first container to which fibroblast cells adhere;
- (ii) re-plating non-adherent cells from (i) in a second container when approximately 15% to 20% of the cells from the cell suspension have adhered to the first container;
- (iii) repeating step (ii) at least two times to enrich for an end population of viable, non-fibroblast, desmin-expressing cells in the second container; and
- (iv) isolating an end population of viable, non-fibroblast, desmin-expressing skeletal muscle-derived myoblasts in the culture.

267. (New) A method of repairing sphincter muscle tissue injury, damage, or dysfunction associated with stress urinary incontinence, comprising:

introducing an enriched population of autologous skeletal muscle-derived myoblasts into a site of injured, damaged, or dysfunctional sphincter muscle tissue of a recipient in need thereof, in an amount effective to repair the injured, damaged, or dysfunctional sphincter muscle tissue to ameliorate stress urinary incontinence.

Applicants: Michael B. Chancellor et al.
U.S. Serial No.: 09/302,896
Filing Date: April 30, 1999

Docket No.: PIT-010
(Formerly: 2710-4007US1)

268. (New) The method according to claim 267, wherein the skeletal muscle-derived myoblasts are histocompatibly-matched with the recipient in need of treatment.
269. (New) The method according to claim 267, wherein the skeletal muscle-derived myoblasts are introduced in a composition comprising a physiologically acceptable medium.
270. (New) The method according to claim 267, wherein the skeletal muscle-derived myoblasts are introduced in an amount of about 10^5 to 10^6 cells per cm^3 of tissue to be treated in a physiologically acceptable medium.
271. (New) The method according to claim 267, wherein a cloned population of the skeletal muscle-derived myoblasts is introduced into the recipient.
272. (New) The method according to claim 267, wherein the skeletal muscle-derived myoblast cells are subjected to a cytokine or growth factor selected from the group consisting of basic fibroblast growth factor (b-FGF), insulin-like growth factor (IGF), and nerve growth factor (NGF) prior to introducing the skeletal muscle-derived myoblasts into the recipient.
273. (New) The method according to claim 267, further comprising isolating the skeletal muscle-derived myoblasts according to a culture method comprising:
- (i) plating a suspension of skeletal muscle cells in a first container to which fibroblast cells adhere;
 - (ii) re-plating non-adherent cells from (i) in a second container when approximately 15% to 20% of the cells from the cell suspension have adhered to the first container;
 - (iii) repeating step (ii) at least two times to enrich for an end population of viable, non-fibroblast, desmin-expressing cells in the second container; and
 - (iv) isolating an end population of viable, non-fibroblast, desmin-expressing skeletal muscle-derived myoblasts in the culture.

+ Attached to Interview Summary